Section 13. Premarket Notification 510(k) Summary

FEB 25 2014

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K132389

Applicant Information:

Date Prepared:	February 25, 2014
Name:	Mauna Kea Technologies
Address:	9 rue d'Enghien F-75010 Paris, France
Phone:	+33 1 48 24 03 45
Fax:	+33 1 48 24 12 18
Contact Person:	Michael A Daniel, Consultant
Phone Number:	(415) 407-0223
Office:	(925) 254-5228
Facsimile Number:	(925) 254-5187

Device Information:

Device Trade Name:	Cellvizio® 100 Series System and Cellvizio® System with Confocal Miniprobes™
Common Name:	Endoscope and Accessories
Classification Name(s):	Confocal Optical Imaging
Product Code/ Regulation:	OWN / 21 CFR 876.1500
Classification:	Class II

Predicate Devices:

- Regarding the Cellvizio Confocal Imaging System, the Cellvizio 100 Series™ System has been cleared in K111047.
- Regarding the Imaging System and the Confocal Miniprobes equivalence, the Uroflex™B and CystoFlex™F Confocal Miniprobes are identical in design and materials to the AQ-Flex 19 Confocal Miniprobe, most recently cleared through K123676.
- Regarding the compatibility of the access during urological procedures and the visualization and examination of the urinary tract, the following cystoscopes and ureteroscope:
  1. Flexible CystoNephroscope (K043022 from Stryker)
  2. Cysto-Urethroscope "E-Line" (K011496 from Richard Wolf)
  3. PolyScope Flexible Endoscope (K091962 from Lumenis, Inc.)

Device Description:

The subject devices, "Uroflex™B" and "CystoFlex™F" are identical in design and materials to the previously-cleared AQ-Flex 19™ Confocal Miniprobe (K123676), except for the length of their fiber bundle and their reprocessing methods.

Indications for Use:

The Cellvizio® 100 Series System with Confocal Miniprobes is a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues.

The Uroflex™B and CystoFlex™F Confocal Miniprobes can be used within anatomical tracts, i.e. Urinary, including, but not limited to, urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.

Confocal Miniprobe™	Endoscope or accessory
UroFlex™ B	Cystoscope or ureteroscope with operating channel internal diameter ≥ 1.0mm (3 Fr)
CystoFlex™ F	Flexible Cystoscope with operating channel internal diameter ≥ 1.0mm (3 Fr)

Comparison to Predicate Devices:

No change is being made to the design and the fundamental technology and operating principle of the previously-cleared AQ-Flex™ 19 Confocal Miniprobe used in this submission as a predicate device (K123676). The Uroflex™B and the CystoFlex™F are identical to this predicate device, only differing by the length of their fiber bundle (3m for the Uroflex™B and 2m for the CystoFlex™F instead of 4m for the AQ-Flex™ 19) and their reprocessing methods (disinfection instead of sterilization for the CystoFlex™F). The indication for use is being expanded to include visualization of urinary tract during endoscopic procedures.

Verification and validation testing have shown that the Uroflex™B and CystoFlex™F Confocal Miniprobes are compatible with cystoscopes, ureteroscopes or endoscopic accessories with operating channels of diameter > 0.91 mm designed and commonly used to image the urinary tract during endoscopic procedures.

Summary:

The Uroflex™B and CystoFlex™F Confocal Miniprobes, when used as part of the Cellvizio 100 Series and the Cellvizio Systems, have been shown to be substantially equivalent to cleared predicate devices, such as the AQ-Flex 19 Confocal Miniprobe, and can be used as intended to image the internal microstructure of tissues in the urinary tract during endocsopic procedures. This previously cleared Miniprobe have been verified to be compatible with cystoscopes, cysto-nephroscopes and ureteroscopes, designed to be used in these applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Mauna Kea Technologies
% Michael A. Daniel
Regulatory Consultant
Daniel & Daniel Consulting
8 Snowberry Court
Orinda, CA 94563

Re: K132389
Trade/Device Name: Cellvizio® 100 Series System and Cellvizio® System with Confocal Miniprobes™
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OWN
Dated: January 17, 2014
Received: January 22, 2014

Dear Michael A. Daniel,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132389

Device Name
Cellvizio® 100 Series System and Cellvizio® System with Confocal Miniprobes™

Indications for Use *(Describe)*

The Cellvizio® 100 Series System with Confocal Miniprobes is a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues.

The Uroflex™ B and CystoFlex™ F Confocal Miniprobes can be used within anatomical tracts, i.e., urinary, including, but not limited to, urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.

Confocal Miniprobes™	Endoscope or accessory
UroFlex™ B	Cystoscope or ureteroscope with operating channel internal diameter ≥ 1.0mm (3 Fr)
CystoFlex™ F	Flexible Cystoscope with operating channel internal diameter ≥ 1.0mm (3 Fr)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
2014.02.25 12:23:47 -05'00'